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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/051,652	01/15/2002	Manuel L. Penichet	0180.0026	8739

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EXAMINER	
SANG, HONG	
ART UNIT	**PAPER NUMBER**
1643	

DATE MAILED: 08/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/051,652	PENICHET ET AL.	
	Examiner	Art Unit	
	Hong Sang	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 July 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) *1-22* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *15 Janurary 2002* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *3/12/02*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

RE: Penichet et al.

1. The examiner of your application in the PTO has changed. To aid in correlating of any papers for this application, all further correspondence regarding this application should be directed to Hong Sang, Art Unit: 1643.

2. Applicant's election of Group III Claims 23-28 and species election of antibody (including antibody fragments and scFv) and transferrin receptors in the reply filed on July 22, 2005 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

3. Due to restriction and species election, for the art rejection, Claims 23, 25, 26 and 28 are examined to the extent that a targeting moiety is an antibody (including antibody fragments and scFv) and Claims 23-26 and 28 are examined to the extent that the cell surface targets are transferring receptors.

4. Claims 1-28 are currently pending. Claims 1-22 are withdrawn from further consideration as being drawn to nonelected inventions.

5. Claims 23-28 are under examination.

6. The information disclosure statement (IDS) filed on 3/12/2002 has been considered. A signed copy is attached hereto.

Claim Rejections - 35 USC § 112, 1st paragraph

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 23-25, 26 and 28 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

In the instant case, the claims are inclusive of a genus of compositions that bind to a genus of cell surface proteins or carbohydrates. However, the written description in this case only sets forth a composition comprising an anti-transferring receptor antibody-avidin conjugate, therefore the written description is not commensurate in scope with the claims which read on a composition comprising any targeting moiety or ligand to the generic class of cell surface proteins or carbohydrates claimed. The Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement make clear that the written description requirement for a claimed genus may be satisfied through sufficient description of a representative number of species by actual reduction to practice, reduction to drawings, or by disclosure of relevant, identifying characteristics, i.e., structure or other physical and or chemical properties, by functional characteristics coupled with a known or disclosed correlation between function and structure, or by a combination of such identifying characteristics, sufficient to show the applicant was in possession of the genus (Federal

Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001, see especially page 1106 3rd column).

The claims are drawn to a composition that binds to a genus of cell surface proteins or carbohydrates. A "cell surface protein or carbohydrate" encompasses any cell surface protein or any cell surface carbohydrate with the functional activity of binding to a ligand. The claims do not require that the cell surface protein or carbohydrate possesses any particular biological function or any particular structural feature. A "targeting moiety or ligand" encompasses a variety of molecules with different structures and functions such as proteins (including antibodies), antisense nucleic acids, small peptides, organic compounds, inorganic ions, etc. The specification discloses a composition comprising an antibody-avidin conjugate specific for a transferring receptor. Applicant does not appear to have reduced to practice any other composition comprising a targeting moiety-avidin or a ligand-avidin to any other cell surface proteins or carbohydrates. Neither has applicant provided sufficient descriptive information such as definitive structural or functional features that are common to the genus of targeting moiety or ligand and genus of cell surface proteins or carbohydrates. That is, the specification provides neither a representative number of targeting moiety or ligand and cell surface proteins or carbohydrates that encompass the genus of targeting moiety or ligand and the genus of cell surface proteins or carbohydrates nor does it provide a descriptive of structural features that are common to the targeting moiety or ligand and cell surface proteins or carbohydrates. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and

because the genus is highly variant (i.e. which includes receptors and carbohydrates), the disclosure of a single species is insufficient to describe a highly variant genus. Thus the genus of molecules encompassed by the term "cell surface protein or carbohydrates", and "targeting moiety or ligand" recited in the claims is extensive and the artisan would not be able to recognize that applicant was in possession of the invention as now claimed.

Consequently, Applicant was not in possession of the instant claimed invention. See Regents of the University of California v. Eli Lilly and Co. 119 F.3d 1559, 43 USPQ2d 1398 (Fed. Cir. 1997). Adequate written description of genetic material "'requires a precise definition, such as by structure, formula, chemical name, or physical properties,' not a mere wish or plan for obtaining the claimed chemical invention." Id. 43 USPQ2d at 1404 (quoting Fiers, 984 F.2d at 1171, 25 USPQ2d at 1606). The disclosure must allow one skilled in the art to visualize or recognize the identity of the subject matter of the claim. Id. 43 USPQ2d at 1406. A description of what the genetic material does, rather than of what it is, does not suffice. Id.

Therefore, only an antibody and transferrein receptors but not the full breadth of "targeting moiety or ligand", and "cell surface protein or carbohydrate" meet the written description provision of 35 U.S.C. § 112 first paragraph. Applicant is reminded that *Vas-Cath* makes clear that the written description provision of 35 U.S.C. §112 is severable from its enablement provision (see page 1115).

Applicant is directed to the Guidelines for the Examination of Patent Applications Under the 35 U.S.C. 112, ¶ 1 "Written Description" Requirement, Federal Register, Vol. 66, No. 4, pages 1099-1111, Friday January 5, 2001.

Applicant is invited to point to clear support or specific examples of the claimed invention in the specification as-filed.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 23-28 are rejected under 35 U.S.C. 102(b) as being anticipated by Penichet et al (J. Immunol. 1999, 163: 4421-4426, see IDS).

Claims 23-28 are drawn to a composition for use in treating cells to induce apoptosis and/or inhibit cell proliferation wherein said cells include cell surface proteins or carbohydrates, said composition comprising: a cytotoxic agent consisting of a targeting moiety and an avidin moiety wherein said target moiety is capable of binding to one or more of said cell surface proteins or carbohydrates; and a pharmaceutical acceptable carries, wherein said targeting moiety is an antibody, antibody fragment, scFv, the cell surface protein is transferring receptors, said targeting moiety is a fusion protein.

Penichet et al. teach an antibody-avidin fusion protein specific for the transferring receptor and that this fusion protein showed much longer serum half-life than the chemical conjugate between OX-26 and avidin (see abstract, and Figure 1). Penichet et al. also teach a pharmaceutical carrier for study of pharmacokinetics and brain delivery of the antibody-avidin fusion proteins (see page 4423, left column, 2nd paragraph, lines 4-8). Although Penichet et al. do not teach its use for treating cells to induce apoptosis and/or inhibit cell proliferation, the claims are drawn to the product *per se* and inherently, such a composition or fusion protein would induce apoptosis and/or inhibit cell proliferation. Thus, the claimed composition appears to be the same as the prior art. The office does not have the facilities and resources to provide the factual evidence needed in order to establish that the product of the prior art does not possess the same material, structural and functional characteristics of the claimed product. In the absence of evidence to the contrary, the burden is on the applicant to prove that the claimed product is different from those taught by the prior art and to establish patentable differences. See In re Best 562F.2d 1252, 195 USPQ 430 (CCPA 1977) and Ex parte Gray 10 USPQ 2d 1922 (PTO Bd. Pat. App. & Int. 1989).

Claim Rejections - 35 USC § 102

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

12. Claims 23-28 are rejected under 35 U.S.C. 102(a) as being anticipated by WO 01/07084 (see IDS).

Claims limitations are set forth above.

WO 01/07084 claims a fusion protein comprising a first segment and a second segment: the first segment comprising a variable region of an antibody that recognizes an antigen on the surface of a cell and further comprises at least one domain of a constant region of an antibody; and the second segment comprising a protein domain selected from the group consisting of avidin, an avidin mutein, a chemically modified avidin derivative, streptavidin, etc (Claim 1), wherein, the receptor is a growth factor receptor (Claim 4), wherein the growth factor receptor is transferring receptor (Claims 6-7), wherein the entire constant region of the heavy chain of the antibody is present and the second segment is located to the carboxyl-terminal side of the C_H3 region in the fusion protein (Claim 16). WO 01/07084 further teaches a pharmaceutical carrier for study of pharmacokinetics and brain delivery of an antibody-avidin fusion protein (see page 29, second paragraph, lines 20-25). Although WO 01/07084 does not teach its use for treating cells to induce apoptosis and/or inhibit cell proliferation, the claimed product in WO 01/07084 is considered same as instant product because of the reasons set forth above (see paragraph 10).

Conclusion

13. No claims are allowed.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Hong Sang whose telephone number is (571) 272 8145. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry R. Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER YAEN
PATENT EXAMINER

Hong Sang
Art Unit 1643
Aug. 12, 2005